EXHIBIT B

8

ABBOTT LA RATORIES
RESEARCH DEPARTMENT

BOOK [illegible]. 68,160

PROJECT HCV combo Assay

EXP. OR CODE NO. Ab, Ag Blended ags ind conj.

This is the first demonstration of a Combination antibody/Ag test for HCV.

N/A 08/31/00 21:29:16 L JIANG

Blended Up and Blended conjugate

Up: HC31 (DF=3 Coating conc: 200ug/ml) + C11-14 (0.09% 0.4um)
Conjugate: C11-10 (100ng/ml 1:16) + 6A52B (1/5dilution in HIV combo CD)
Washes: HIV ag transfer wash Dev lot 5/ final wash : HCv Ag prep
SDB: 6A52Q
Up diluent: 18498 HCv Ab assay up diluent
S/A configuration: HCV

SubA	SubB	Combo Assay Mean counts	P/N	Ab Assay Mean Counts 08/28/00	P/N
				33952	8.64
1502	1923	1712.5	2.17	3930.17	
808	852	780			
755	745				
719		719	0.91	4618.75	1.23
1157	1083	1110	1.41	38800.67	9.36
9785	9035	9410	11.91	147307.5	37.46
7972	8237	8104.5	10.26		
2550	3839	3094.5	3.92		
5227	5280	5258.5	6.66		
842	899	870.5	1.10	1427	0.36
1954	1773	1863.5	2.36	2058.5	0.52
2552	2463	2507.5	3.17	1704.5	0.43
3806	3507	3556.5	4.50	1716.5	0.44
2882	3120	3001	3.80	1507.5	0.38
2055	2280	2172.5	2.75	1671.5	0.43
	3707	3707	4.69	1665	0.42

3.17

cont. on pg # 10

Samples	P/N
PC (Ab)	55.82
NC (Ab)	88.36
99800 Panel A	28.63
E2 1/20 dil	33.48
Promed 9992161	56.58
PC JV 016829	84.19
PC JV017220	41.90
Sero-Tec panel #3	46.13
4	61.13
5	
6	
7	
8	
9	

Ag Assay Mean counts 08/24/00	P/N
4409.83	79
6980.5	
681.5	
2645	
4706.5	
5071	
4258	
2853	
4829	

1277

21511

A

6

1023
V COMBO ASSAY

As the first Blend up and Conj. results are encouraging. Dilute Conj more for Next run.

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ABBOTT L'ˀORATORIES
RESEARCH DEPARTMENT

BOOK NO. 68,160

PROJECT HCV combo Assay

EXP. OR CODE NO. Cont. from page #8.

DESCRIPTION OF PANEL MEMBERS -

NC - negative control - pooled plasma individually screened as negative for HCV antibodies by a commercialized assay- **Code: 6A52E. Prism HCv Ab Assay Negative Calibrator.**
PC - positive control - pooled anti-HCV positive plasma diluted in negative control . **Code: 6A52F. Prism HCV Ab Assay Positive Calibrator.**

99800 - Plasma(human) Recalcified Negative Bulk.

Panel A - an anti-HCV positive plasma that has been diluted in negative control to provide a mid range sample to cutoff in the PRISM antibody assay.

E2 1/20 - an anti-HCV positive sample that has been diluted in negative control - the E2 antibody panel was utilized to titrate the potency of HCV E2 antigen coated microparticles

Promed 9992161 - an antibody positive sample obtained from ProMeDx (Plainville, MA)

PC JV 16929 - Sero-Tec HCV RNA positive human plasma .
PC P JV17220 - Sero-Tec HCV RNA positive human plasma .

SeraTec Panel members 3-9 - serial bleeds obtained from a plasma donor identified at SeraTec as being anti-HCv negative and HCV antigen positive.

A panel of specimens previously characterized as having antibodies to HCV or being negative for antibodies to HCV but positive for HCV RNA and HCV antigens were tested in a preliminary HCV combination antibody.antigen test.

Reagents utilized in combo test
Microparticles specific for HCV antigen detection (up's coated with C11-14 as described on RB: 67093 page 100) and microparticles specific for HCV antibody detection (up's coated with HCV recombinant protein HC 31 as described on RB: 68160page 2) were blended to produce a solid phase that would allow simultaneous detection of HCV antibodies and HCV antigens in a single reaction well. (The blended microparticles contained 0.19% solids, representing a mixture of 0.09% up's coated with C11-14 and 0.1% coated with HC31). The conjugates were also a mixture of two separate acridinium labeled proteins. Acridinium labeled C11-10 was utilized for HCV antigen detection (recognizing HCV antigens captured on the C11-14 microparticles) and an acridinium labeled monoclonal antibodies against biotin -labeled gaot anti-human IgG (presented as a pre-complex - see RB: 52226m301) was utilzied to detect human anti-HCV IgG bound to the HC-31 coated microparticles.

S Expt.

6/4/98 more Description

Results

The panel described above was run on 3 different PRISM-based assays. One of the assays detected HCV antibodies, a second test detected HCV antigens and a third test (the combo assay) detected both HCV antibodies and HCV antigens.
Sampels have a positive to negative ratio (P/N) ratio of 3.0 or greater were considered positive. The data presented in the table on RB68160page 8 indicate that the combo assay allows detection both of antibody positive samples (e.g. panel E2 1/20, ProMed 9992161, PC JV 016929 and PC JV 17220) and HCV antigen positive samples (Sera Tec panel members 5-9). Thus, this single combo assay performed in a single reaction well detects most of the samples that were positive in two separately performed assays, the HCV antibody test and the HCV antigen test. This is the first demonstration of a combo HCV antibody / HCV antigen test at Abbott Laboratories, and is the first example of the HCV antibody /antigen combo test ideas presented in Redbook 61,959: pages 1-8. Other iterations of the HCV combo test will be presented over the next several weeks/months.

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ABBOTT LABORATORIES

RESEARCH DEPARTMENT

PROJECT HCV combo Assay. *

EXP. OR CODE NO.

Title: HCV combo Assay: Blended up and Blended conjugate

Purpose: To blend the HCV core peptide coated ups, NS3NS4 coated up, c11-14 coated ups together and c11-10 , aHigG Acr* conjugate together for HCV combo first demonstration.

Materials and Samples
RB: 68160001 and 68160011.

(Core peptide Ag + NS3NS4 for Ab Detection)
c11-14 mAb coated ug for Ag Detection)

Preparation:
Add Avidin 11-28 (df=20) and NS3NS4 (df=10) and c11-14 (0.09% seradyn)
Add conjugate c11-10 (50ng/ml) and aHigG Acr* (10ng/ml)

Results:

HCV Combo (11-28, NS3NS4,c11-14 c11-10, aHigG) 9 12

Conclusions:
The combo assay successfully detected all the Ab pos. samples and Ag positive samples.

Next Steps:
Dilute the AhIgG conjugate to 7ng/ml and 2 ng/ml

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HCV COMBO 11-28,NS3NS4 C11-14 C11-10 AHIGG

HCV Combo Assay

Blended ups: HCv Core Bio-11-28(Df=20)+ NS3NS4 HCV Ag (DF=10)+ C11-14(0.09%)
Conjugate: c11-10(5ong/ml) + aHIgG Acr*(10ng/ml)
Washes: HCV Ag Assay Transfer: HIV Ag Devlot5, Final wash: HCV Ag final wash prep 8/1/2000
SDB: HCV Ab (6A52Q)
S/A (1023) configuration: HCV

	SubA	SubB	Mean	P/N
PC (Ab)	3454	3656	3555	4.84
PC (Ag)	5303	6014	5658.5	7.71
PC(Ag)	4288	3722	4005	5.46
NC(99800)	637	831	734	
E2 1/20	12480	13092	12786	17.42
ProMed 9990196	11449			15.60
9990164	15	No conjugate was added		
9990162	10060		10060	13.71
9990212	13925		13925	18.97
Sero-Tec panels #3	956		956	1.30
4	2347		2347	3.20
5	3400		3400	4.63
6	4673		4673	6.37
7	4265		4265	5.81
8	3045		3045	4.15

*Materials: Code/List/Desc/Lot see RB: 68160

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ABBOTT LABORATORIES
RESEARCH DEPARTMENT

BOOK NO. 68,160

PROJECT

EXP. OR CODE NO. Cont. from page #17

1023 6 A N/A 09/15/00 11:10:02 L JIANG
BO SEROCONVERSION

ups
11-28+NS3NS4+C11-14

Conjugate
50ng/ml + 7ng/ml
01-10, vH16*
57051

	SubA	SubB	Mean	P/N
NC	452	456	454.00	
E2 (1/20)	7753	7804	7778.50	17.13
PC (Ag)	4462	4407	4434.50	9.77
9990212	7611		7611.	16.76
9996196	6878		6878	15.15
9996164	5133		5133	11.31
Sero-Tec panel #3	1257		1257	2.77
4	2640		2640	5.81
5	2870		2870	6.32
6	4917		4917	10.83
BBI HCv sero 907 #1	5595		5595	12.32
2	2707		2707	5.96
3	2614		2614	5.76
4	2701		2701	5.95
5	2343		2343	5.16
6	4443		4443	9.79
7	8147		8147	17.94

ups
11-28+NS3NS4+C11-14

Conjugate
50ng/ml + 2ng/ml
" "

	SubA	SubB	Mean	2ng/ml P/N	7ng/ml P/N
NC	277	246	261.50		17.13
E2 (1/20)	2831	2879	2855.00	10.92	9.77
PC (Ag)	4213	4099	4156.00	15.89	16.76
9990212	2773		2773	10.60	15.15
9996196	2249		2249	8.60	11.31
9996164	1918		1918	7.33	2.77
Sero-Tec panel #3	927		927	3.54	5.81
4	2299		2299	8.79	6.32
5	3002		3002	11.48	10.83
6	5112		5112	19.55	12.32
BBI HCv sero 907 #1	3754		3754	14.36	5.96
2	3363		3363	12.86	5.76
3	2230		2230	8.53	5.95
4	2404		2404	9 19	5.16
5	1743		1743	6.67	9.79
6	2084		2084	7.97	17.94
7	1566		1566	5.99	

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PROJECT

EXP. OR CODE NO. Cont. from page #18

BOSTON BIOMEDICA, INC.

Anti-HCV Seroconversion Panel (PHV907)

HCV Genotype 1A

Panel Member	Bleed Date	Day No.	ABBOTT 3.0 HCV S/CO	ORTHO HCV 3.0 S/CO	Combo data Conj @7 ng/ml S/N	Combo data Conjug @ 2 ng/ml S/N	Abbott Ag Only Tst s/co(1)	Roche Amplicor RNA copies/ml
PHV907-1		0	0.1	0.0	12.3	14.4	25.68	3 x 10e6
PHV907-2		4	0.1	0.0	6.0	12.9	20.41	2 x 10e6
PHV907-3		7	0.1	0.0	5.8	8.5	17.88	1 x 10e6
PHV907-4		13	0.2	0.1	6.0	9.2	15.98	1 x 10e6
PHV907-5		18	0.8	0.5	5.2	6.7	6.88	1 x 10e6
PHV907-6		21	1.4	1.0	9.8	8.0	7.90	1 x 10e6
PHV907-7		164	>5.0	>5.0	18.0	6.0	0.70	nd

Data above demonstrates on seven member seroconversion panel, that HCV RNA and HCV Antigens can be detected from the first bleed date through the sixth bleed date, but the seventh bleed date is negative for HCV antigen. The antibody tests Ortho 3.0 and Abbott 3.0 failed to detect antibodies in the first five bleed dates (through).

The combo test detected exposure to HCV for all seven bleed dates.

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RESEARCH ['ARTMENT

BOOK NO. 68,160

PROJECT PRISM HCV Ag/Ab combo

EXP. OR CODE NO. HCV combo Assay Random Donor Population

Reagents: Same as Exp[t] # 68160017.

1023 6 A N/A 09/18/00 11:00:17 L JIANG

OMBO SMALL POP

HCV Combo Assay Population

	SubA	SubB	Mean	P/N	Cutoff(3nc)	S/CO	Cutoff (2.5nc)	S/CO	Cut off (2.33nc)	S/CO
PC (Ag)	3737	3854	3795.5	15.30	744	5.10	620	6.12	577.84	6.57
E2 (1/20)	2949	2785	2867	11.56		3.86		4.62		4.96
NC (99800)	214	282	248							
GCRBC plasma #1	182					0.24		0.29		0.31
2	163					0.22		0.26		0.28
3	292					0.39		0.47		0.51
4	172					0.23		0.28		0.30
5	265					0.36		0.43		0.46
6	172					0.23		0.28		0.30
7	271					0.36		0.44		0.47
8	329					0.44		0.53		0.57
9	200					0.27		0.32		0.35
10	247					0.33		0.40		0.43
11	196					0.26		0.32		0.34
12	246					0.33		0.40		0.43
13	432					0.58		0.70		0.75
14	214					0.29		0.35		0.37
15	161					0.22		0.26		0.28
16	215					0.29		0.35		0.37
17	140					0.19		0.23		0.24
18	227					0.31		0.37		0.39
19	284					0.38		0.46		0.49
20	209					0.28		0.34		0.36
21	200					0.27		0.32		0.35
22	185					0.25		0.30		0.32
23	248					0.33		0.40		0.43
24	209					0.28		0.34		0.36
25	291					0.39		0.47		0.50
26	241					0.32		0.39		0.42

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